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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,121	11/27/2000	Gautam Khurana	07039-296001	5932

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EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/723,121

Applicant(s)

KHURANA ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-12,14-27 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11,12 and 14-20 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,10,21-27,29-40 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 3-12, 14-27 and 29-40 are pending in the application.

This Office Action is in response to the Amendment filed on 6/25/03.

#### ***Response to Amendment***

The rejection of claims 11, 12 and 14 under 35 U.S.C.103 (a) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 21-27, 29 and newly added claims 37-39 under 35 U.S.C.112 2<sup>nd</sup> paragraph is maintained for reasons set forth of the record mailed on 12/23/02 and further discussed below.

The rejection of claims 1, 3 and 10 under 35 U.S.C.102 (e) is maintained for reasons set forth of the record mailed on 12/23/02 and further discussed below.

Claims 1, 3-5, 10 and 21 are rejected under 35 U.S.C. 103 (a) for reasons discussed below.

Newly added claims 30-32, 34 and 35 are rejected under 35 U.S.C.102 (b or e) for reasons discussed below.

Newly added claims 31-36 and 40 are rejected under 35 U.S.C.112 2<sup>nd</sup> paragraph for reasons discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 21-27, 29 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to this rejection, Applicants amended claims to recite that the "contact surface is detachably connected to the housing." However, it is still where contact surface is connected. In other words, is the contact surface connected to the first end of the lumen or the second end of the lumen?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by McCall et al.

In response to the rejection, Applicants amended the claims to recite that the gene delivery device is a graspable gene delivery device. The disclosure of the McCall et al. was discussed in detail in the previous office. Applicants' amendment does not overcome the rejection because applying cream to the site of the infection (either wounded or intact skin/mucosa) comprises applying the cream to a finger (a contact surface) and subsequently contacts the finger with cream to the tissue site, wherein such contacting can be moving the

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finger back and forth or in circular motion at the tissue site. Absent evidence to the contrary, a human finger is graspable. Therefore, McCall et al. anticipate the instantly claimed invention.

*New Grounds of Rejection Necessitated by Applicants' Amendment*

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by McCall et al.

The disclosure of McCall et al. is discussed in the previous office action and above.

Briefly, McCall et al teach a method of delivering a ribozyme by formulating it into a cream form and applies it to the affected site. Therefore, McCall disclose the instantly claimed invention.

Claims 31, 32, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Serra et al.

The disclosure of Serra et al. was discussed in the previous office action. Briefly, Serra et al. disclose a mini brush that has soft, flexible bristles with a lumen for delivering pharmaceutical compositions to dissolve a fibrinous obstruction in small vessels (see Figure 1 and 3, and abstract). Serra et al. teach that the distal tubing with brush and the proximal tubing

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are connected by a mandrel or thin tube (see col.3, and Figures 1 and 3). Since the mandrel and the tubing are flexible (see col.2, lines 25-26), the brush is adjustable from 0-180 degree angle. In addition, the proximal tube may easily be fitted to a syringe or conduit tubing depending on the need. Therefore, Serra et al. disclose the instantly claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCall et al.

The teaching of McCall et al. was discussed in detail in the previous office action. However, McCall et al. do not teach delivering DNA by claimed method.

It would have been obvious to one of ordinary skill of art to apply the cream comprising the ribozyme by a cotton swab or sponge in back and forth or circular motion to the site of infection. Although McCall et al. do not teach such method, it would have been obvious to one of ordinary skill of art because it is common practice to apply cream medication, and avoid unnecessary contact with skin (such as finger) for sanitary reason. In this case, the cotton swab or sponge is a graspable gene delivery device with a plurality of fiber or a sponge. Therefore, the invention would have been obvious *prima facie* to one of ordinary skill of art at the time the invention was made.

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Although McCall et al. do not teach delivering DNA by claimed method, it would have been obvious to one of ordinary skill of art that therapeutic DNA such as antisense can also be delivered by this method when made into a cream form. Since DNA and RNA are structural similar compounds, one of ordinary skill of art would have reasonable expectation of success to deliver DNA by the same method to affected tissue site. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Serra et al.

The teaching of Serra et al. was discussed in detail in the previous office action. Serra et al. teach that the distal tubing with brush and the proximal tubing are connected by a mandrel or thin tube (see col.3, and Figures 1 and 3). However, Serra et al. do not teach that the contact surface is detachably connected to the housing.

It would have been obvious to one of ordinary skill of art that the pharmaceutical composition delivering device would have detachable brush that is connected to either the proximal or distal tube. Although Serra et al. do not specify the brush is detachable, it is obvious to one of ordinary skill of art to make the brush detachable for replacement of the brush when it is worn, or change to a different size to fit in a different size blood vessel. Since the brush is connected to through a thin wall tube or a mandrel, one of ordinary skill of art would have reasonable expectation of success to make the connection detachable. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill of art at the time the invention was made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 31-36, it is unclear how the contact surface is connected to the housing. In other words, it is unclear whether the contact surface is connected to the first end, second end, or middle of the housing unit.

Regarding claim 40, it is unclear how a plurality of contact surfaces is connected to the housing in different angle at the same location. In addition, it is also unclear where these contact surfaces are fitted.

### *Conclusion*

Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 11, 12, 14-20 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period



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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

  
JAMES KETTER  
PRIMARY EXAMINER